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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------------------------------------------------------------------|-------------|----------------------|------------------------------------|------------------|
| 09/845,497 | 05/01/2001 | Amina Odidi | 9577-25 LAB | 2340 |
| 7590 Lola A. Bartoszewicz Sim & McBurney 6th Floor 330 University Avenue Toronto, ON M5G 1R7 CANADA | | | EXAMINER PRYOR, ALTON NATHANIEL | |
| | | | ART UNIT 1616 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | | |
| 3 MONTHS | 03/26/2007 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/845,497 | Applicant(s) ODIDI ET AL. | |
| | Examiner Alton N. Pryor | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,6-9,11,15-17 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,6-9,11,15-17,21-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

- I. Rejection of claims 1,6-9,11,15,16,22,24-29,34 under 35 USC 112, first paragraph will not be maintained in light of amendment filed 12/15/06. Applicant has amended claims to recite that it is the capsule, tablet, bead, or pellet which is encapsulated rather than to the encapsulation of only the active ingredient.
- II. Rejection of claims 17,21,23,30,33 under 35 USC 103(a) as being unpatentable over Hirashima (JP 03197421) will be maintained in light of amendment filed 12/15/07. Applicant argues that the amounts of PEG and polymer used in the polymeric film of Hirashima differ from the amounts of PEG and polymer used in the polymeric film disclosed in the instant invention. Applicant also argues that the polymeric film disclosed in instant invention is non-permeable whereas the polymeric film disclosed in Hirashima is semi-permeable. Examiner argues that the amount of both PEG and polymer taught in Hirashima and instant invention only differs by 10% and for this reason it is necessary for the Applicant to show the criticality of these small differences. With respect to the polymer properties, both Hirashima and instant invention employ the same polymers, e.g., cellulose esters. Therefore the cellulose ester taught in Hirashima which is semi-permeable, would have the same property of being semi-permeable in the instant invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1,6-9,15-17,21-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for invention comprising polymeric films: polyvinyl acetate phthalate, methacrylic acid copolymers, does not reasonably provide enablement for the polymeric film being cellulose esters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Note instant invention requires the polymeric film to be non-permeable. The instant invention uses cellulose esters to formulate the non-permeable film. However USPN 6099859 at column 4 lines 10-28 and USPN 6106864 at column 4 lines 32-38 disclose that cellulose esters are semi-permeable rather than non-permeable.

Claims 1,6-9,11,15-17,21-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not explain what is meant by – a non-permeable polymeric film. What does the phrase mean? How is the drug in the film being used?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,6-9,11,15-17,21-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dolan et al (USPN 6106864; 8/22/00) and Dong et al (USPN 5800422; 9/1/98) and Cheng on record (USPN 6099859; 8/8/00). Dolan teaches oral dosage forms of actives such as darifenacin. See column 2 lines 34-52. Dolan teaches that the matrix comprising the active can be formed into a multiparticulate and / or coated with an impermeable coating. See column 2 lines 53-57. Dolan teaches that the multiparticulate cores comprising the actives can also contain cellulose and lactose (compression aids). See column 3 lines 1-7. Dolan teaches that the ingredients can be formulated into a tablet which can be coated with shellac, phthalate derivatives (cellulose acetate phthalate, polyvinylacetate phthalate) as well as with semipermeable coatings such as cellulose esters (ethyl cellulose, cellulose acetate) and acrylic polymers. See column 3 lines 7-38. Dolan does not teach the polymeric coating comprising 1) 5 up to less than 50% by weight polymer, e.g. ethyl cellulose 2) 0.5 to 30% PEG. Dolan is silent to the amount of polymer in the coating. Therefore, in the absence of unexpected results showing the significance of the instantly claimed amount of polymer, the ideal amount of polymer used in Dolan may have fallen within the instant range of polymer amount being claimed. With respect to the polymeric film comprising PEG. Dong discloses the use of PEG in a capsule film coating. Note, Dong uses 25 % PEG in the polymer coating which falls within the instantly claimed range amount. Cheng teaches that PEG is a flux enhancing agent. A flux enhancing agent allows the drug to be released through the pores of the polymeric coating. It would have been obvious to one having ordinary skill in the art to modify the invention of Dolan to include

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the PEG to enhance the release of the drug through the pores of polymeric coating.

Although claims require the polymeric material to be non-permeable, it is noted that the claims employ polymeric films such as cellulose esters and acrylic polymers which are semi-permeable. For this reason the rejection appears to be proper. Note the property of the polymeric coating being soluble at a pH above 5.0 and having an extended release of the active over 12 hours are inherent properties of the polymer (cellulose esters) and PEG being used.

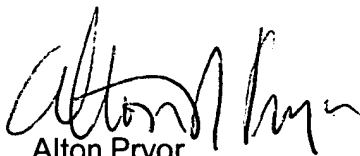
Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Alton Pryor', is written over the printed name.

Alton Pryor
Primary Examiner
AU 1616